Cynthia S. Betz
Mark M. Makhail
McCarter & English, LLP
Four Gateway Center
100 Mulberry St.
Newark, NJ 07102
Telephone: (973) 622-4444

Attorneys for Plaintiffs Pacira Pharmaceuticals, Inc., and Pacira Biosciences, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PACIRA PHARMACEUTICALS, INC., and PACIRA BIOSCIENCES, INC., Plaintiffs, v. eVenus PHARMACEUTICALS LABORATORIES, INC., JIANGSU HENGRUI PHARMACEUTICALS CO., LTD., and FRESENIUS KABI USA, LLC, Defendants.	Civil Action No. 2:23-cv-02367-MCA-JRA

PLAINTIFFS' REPLY IN SUPPORT OF MOTION TO DISMISS WITH PREJUDICE DEFENDANTS' DECLARATORY JUDGMENT COUNTERCLAIM REQUIRING DE-LISTING THE '348 PATENT FROM THE ORANGE BOOK

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Other Authorities

If Defendants had made a contract counterclaim but ignored the operative contract, the only relief would be dismissal. It wouldn't be up for debate. The same applies here. The Federal Circuit has made clear that it is the scope of the NDA that governs the de-listing inquiry, not batch data. Thus, Defendants' pleading, which alleges only specific batch data and does not even reference Pacira's NDA specification, fails under Rule 12(b)(6). Defendants attempt to distinguish *Andrx* and *Sunovion* by injecting irrelevant facts that appear nowhere in the pleadings, a tactic that cannot overcome their fatally defective pleading.

The Court should dismiss the de-listing counterclaim with prejudice.

I. ARGUMENT

A. Defendants Have Failed to Plausibly State a De-listing Counterclaim

1. Defendants' Counterclaim Contains No Allegations Concerning the Scope of Pacira's NDA for EXPAREL®

Under *Andrx* and *Sunovion*, it is the NDA specification, not the actual batch data of the drug product being sold, that governs the de-listing inquiry. Defendants' de-listing counterclaim, however, contains no factual allegation whatsoever concerning the scope of Pacira's NDA for EXPAREL®. Instead, it relies solely on the specific batch data (which is legally irrelevant) in alleging that EXPAREL® does not practice the erucic acid limitations at issue. (*See* ECF No.

103, ¶¶ 277–293; *see also* ECF No. 122 ("Opp.") at 10-11 (highlighting the allegations regarding specific batches of EXPAREL®)).

Defendants urge the Court to take as true its allegation that "[o]n information and belief, Pacira's NDA 022496 does not cover a drug that practices any claim of the '348 Patent." (Opp at 9-10 (citing ECF No. 103, ¶ 291)). But that is not a factual allegation—it is nothing more than "labels and conclusions" that deserves no weight at the pleading stage. *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) ("A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'"); *see also Aljindi v. United States*, 2023 WL 2778689, at *1 (Fed. Cir. Apr. 5, 2023) (". . . conclusory allegations or legal conclusions masquerading as factual conclusions will not suffice to prevent a motion to dismiss."); *Perelman v. Perelman*, 545 F. App'x 142, 146 (3d Cir. 2013) (a counterclaim "must do more than simply provide 'labels and conclusions,' or 'a formulaic recitation of the elements of a cause of action.'") (internal quotations omitted). Even if it were a factual allegation, the Court should disregard it and focus on the actual pleadings, which are devoid of any plausible factual allegation that addresses the necessary requirements of a de-listing claim. *Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009) ("To prevent dismissal, all civil complaints must now set out 'sufficient factual matter' to show that the claim is facially plausible."). Because Defendants failed to allege that that

Pacira's NDA ***does not permit*** Pacira to manufacture batches of EXPAREL® that practice the erucic acid limitation at issue, Defendants' de-listing claim fails as a matter of law. *See Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1376 (Fed. Cir. 2002) (explaining that a de-listing claim hinges on the "relationship of the patent to the drug products and drug substances ***covered by the NDA***") (emphasis added).

Pacira offers an excerpt of the NDA to illustrate that any amendment to the counterclaim would be futile, evidence that Defendants were required to face in their pleading. (ECF No. 115-1 ("Mot.") at 7-8). Defendants try to capitalize on their own failure, arguing that Pacira has "opened the door" to evidence beyond the pleading, and offer a litany of irrelevant, extrinsic factual allegations in hope of surviving dismissal. (Opp. at n.3). Defendants cannot be rewarded for failing to address Pacira's NDA in their pleading. As Pacira advised Defendants before they sought leave to amend, to successfully plead a de-listing claim, Defendants must allege facts with respect to the NDA for EXPAREL®. They didn't. They chose to ignore the law. Defendants cannot use their own faulty pleading to justify the introduction of extrinsic evidence.

In any event, Pacira's NDA unequivocally provides a stability specification which requires the erucic acid concentration in EXPAREL® to be below 310 µg/mL under all conditions, including after storage for six months at 25 ºC as

claimed in the '348 patent. Further, no batches of EXPAREL® can be commercialized and sold without first meeting the specification set forth in the NDA. Thus, Defendants' argument that the NDA "does not speak to whether commercial batches of EXPAREL® must meet any particular specification for erucic acid concentration after storage at 25 ºC for six months" is not only incorrect, but also ignores the fundamental purpose of an NDA.

2. Defendants' Allegations Regarding Actual Batch Data Are Legally Irrelevant Under *Andrx* and *Sunovion*

As explained in the Motion, the analysis for determining whether the propriety of the listing of a patent in the Orange Book is akin to the infringement analysis. "[T]he Hatch-Waxman Act ***requires*** an NDA applicant seeking FDA approval for a drug that enjoys patent protection to identify every patent that claims the drug or a use of the drug that could ***reasonably be asserted in an infringement action***." *Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1318 (Fed. Cir. 2012) (quoting 21 U.S.C. § 355(b)(1)) (emphasis added); *see also, e.g.*, *Dey Pharma, LP v. Sunovion Pharms. Inc.*, 677 F.3d 1158, 1159 (Fed. Cir. 2012) (same); *Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1355 (Fed. Cir. 2008) (same). Defendants have not identified any legal authority that says otherwise.

As the Federal Circuit unequivocally stated in *Andrx*, whether a patent is properly listed in the Orange Book "has nothing to do with" the actual commercial

drug product. *Andrx*, 276 F.3d at 1376, n.4. Defendants agree that "the critical question is the relationship of the patent to the drug products and drug substances covered by the NDA." (Opp. at 15 (citing *Andrx*, 276 F.3d at 1376)). Nevertheless, Defendants devote much of the Opposition to distinguishing *Andrx*, arguing that because the discussion in *Andrx* did not arise in the exact same context as here, the Federal Circuit's guidance in *Andrx* somehow does not apply. (Opp. at 14-17). Not so. Nothing in *Andrx* suggests that batch data for the commercial product may be relevant to a de-listing claim. And certainly, nothing in Defendants' Opposition justifies defiance of the Federal Circuit's mandate that whether a patent is properly listed in the Orange Book "***has nothing to do with***" the actual commercial drug product.

Similarly, Defendants' discussion regarding the FTC's investigation of Biovail, the brand company in *Andrx*, is a red herring. (Opp. at 16-17). It has no bearing on the substantive requirements of a de-listing claim, and the Federal Circuit—not the FTC—is binding authority. Defendants' Opposition swamps the Court with unrelated factual discussions of *Andrx*, attempting to distract the Court from the test for the relevant considerations of a de-listing claim. But Defendants have not raised any legal argument that denies the general applicability of *Andrx*.

Importantly, the Federal Circuit's guidance in *Andrx* is consistent with the *Sunovion* framework, the controlling legal standard for a patent infringement claim

under the Hatch-Waxman Act, which provides that "an ANDA specification defining a proposed generic drug . . . will control the infringement inquiry." *Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1279 (Fed. Cir. 2013). That is exactly the case here. Pacira's NDA includes a stability specification for erucic acid of not more than 310 µg/mL after storage for six months at 25 ºC, which speaks directly to the erucic acid limitation at issue. (Mot. at 7). Defendants argue that *Sunovion* does not apply because it relates to infringement, not whether a patent is properly listed in the Orange Book. (Opp. at 17). That is legally incorrect, as the Federal Circuit has tied the substantive requirements for Orange Book patent listing closely to infringement inquiry. Defendants do not dispute that under the controlling *Sunovion* framework, so long as the NDA includes a specification that ***allows for*** a product to be sold to practice the patent claim, infringement can be established. (*See* Opp. at 17); *Sunovion*, 731 F.3d at 1279. Applying this principle, EXPAREL® practices the erucic acid limitation of the '348 patent, so long as the NDA ***allows for*** the commercial EXPAREL® to do so.

Thus, Defendants' factual allegations, which rely exclusively on specific batches of EXPAREL® that were manufactured and/or sold, are legally irrelevant to their de-listing counterclaim and should not be given any weight, even if accepted as true.

3. The Court Need Not Resolve Any Claim Construction Dispute to Dismiss the De-listing Counterclaim

Defendants' counterclaim must be dismissed under any claim construction because their complete failure to address Pacira's NDA is fatal. Undeterred, Defendants argue that there is a claim construction issue that would prevent dismissal. (Opp at 8-9). Impossible. As discussed above, the Court can readily dismiss the counterclaim because Defendants fail to plead any plausible factual allegations that speak to the substantive elements of a de-listing claim. (*See* ECF No. 103, ¶¶ 277–293). Particularly, there is no allegation whatsoever concerning the scope of Pacira's NDA for EXPAREL®. Thus, even if the Court adopts Defendants' incorrect claim construction and takes as true the allegation that "at least 50% of EXPAREL batches do not have the required erucic acid concentration," Defendants still fail to state a claim, because it is the scope of the NDA that governs the inquiry. The Court does not need to engage in any claim construction analysis—let alone arguments that Defendants failed to raise at the *Markman* stage—to dismiss the de-listing counterclaim.

B. Defendants' Policy Arguments Have No Merit

The Federal Circuit has established that under the *Sunovion* framework, it is the scope of the NDA (particularly, the specification provided in the NDA), not the actual batch data of the commercial product, that controls the analysis of whether a drug product practices a patent claim. As a last resort to avoid dismissal,

Defendants take issue with this controlling law, floating a policy argument that the *Sunovion* framework would have allowed a brand company "to list a patent in the Orange Book for a drug product approved by the FDA, even if the patent does not cover the actual commercial product sold under the NDA." (Opp. at 18). Defendants argue no less than for this Court to ignore the Federal Circuit.

Moreover, Defendants' contention that *Sunovion* does not apply to an infringement claim based on a patent not properly listed in the Orange Book is premature. (Opp. at 19). Here, Defendants have failed at step zero—they could not even plausibly state a claim that the '348 patent is not properly listed in the Orange Book.

II. CONCLUSION

Accordingly, Pacira respectfully requests that the Court dismiss Defendants' de-listing counterclaim with prejudice.

Dated: May 13, 2024

/s/ Cynthia S. Betz
Cynthia S. Betz
Mark M. Makhail
MCCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry St.
Newark, NJ 07102
Telephone: (973) 622-4444
cbetz@mccarter.com
mmakhail@mccarter.com

Michael T. Zoppo
FISH & RICHARDSON P.C.
7 Times Square, 20th Floor
New York, NY 10038
Telephone: (212) 765-5070
Facsimile: (212) 258-2291
zoppo@fr.com

Thomas P. Scrivo
Young Yu
O'TOOLE SCRIVO, LLC
14 Village Park Road
Cedar Grove, NJ 07009
Telephone: (973) 239-5700
tscrivo@oslaw.com
yyu@oslaw.com

Corrin N. Drakulich (*pro hac vice*)
FISH & RICHARDSON P.C.
1180 Peachtree Street NE, 21st Floor
Atlanta, GA 30309
Telephone: (404) 892-5005
Facsimile: (404) 892-5002
drakulich@fr.com

Deanna J. Reichel (*pro hac vice)*
FISH & RICHARDSON P.C.
60 South 6th Street, Suite 3200
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696
reichel@fr.com

Karrie Wheatley (*pro hac vice*)
FISH & RICHARDSON P.C.
909 Fannin Street, Suite2100
Houston, TX 77010
Telephone: (713) 654-5300
Facsimile: (713) 652-0109
moran@fr.com

Jonathan E. Singer (*pro hac vice*)
FISH & RICHARDSON P.C.
12860 El Camino Real, Suite 400
San Diego, CA 92130
Telephone: (858) 678-5070
Facsimile: (858) 678-5099
singer@fr.com

Attorneys for Plaintiffs Pacira Pharmaceuticals, Inc., and Pacira BioSciences, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on May 13, 2024, I caused to be served by electronic mail a true and correct copy of the foregoing documents upon all counsel of record.

/s/ Cynthia S. Betz
Cynthia S. Betz